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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,522	09/14/2004	Hidetoshi Hamamoto	2004-1425A	1134
513 7590 01/06/2009 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021				
EXAMINER				
WEBB, WALTER E				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
01/06/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/507,522

**Applicant(s)**

HAMAMOTO ET AL.

**Examiner**

WALTER E. WEBB

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6,7,10 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,7,10 and 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' arguments, filed 9/9/2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112--previous***

Claim 13 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that use of the term macrogol does not render claim 13 indefinite since it became generic, and is used as the trivial name for polyethylene glycol. However, applicant has provided no evidence that "macrogol" has become generic. "Macrocols" seem to come in grades, e.g. "Macrogol 200." Therefore, it is doubtful that the term has become generic over the entire class of polyethylene glycols, irrespective of weight. Furthermore, there is no reason applicant cannot use the term "polyethylene glycol" if it is really synonymous with "macrogol". Accordingly, the rejection is maintained.

#### ***Claim Rejections - 35 USC § 102--new***

Claims 1, 2, 6, 7 and 13 are rejected under 35 U.S.C 102(b) as being anticipated by Mizobuchi et al., (WO 1998/058651 using US 6,268,355 as English Translation)

Mizobuchi et al. teach a composition comprising polyacrylic acid (uncrosslinked water-soluble polymer) at 9% by wt., glycerin (bactericidal agent) at 10% by wt., macrogol 200 (fluidizing agent) at 20% by wt., and aluminum magnesium metasilicate (crosslinking agent) at 2% by wt., as per claims 1, 2, 7 and 13. (See col. 7, Table 4 of the '355 patent.) The composition does not contain water, so the moisture content less than 3% as per claim 1. The reference teaches sodium polyacrylate, as per claim 6. (See col. 3, line 42.)

The polymer is in sol (uncrosslinked) state prior to use insofar as it has not been crosslinked with said crosslinking agent.

The sodium polyacrylate of Mizobuchi would simultaneously show phase transition to gel after the preparation absorbs exudation in a wounded area of the skin, since sodium polyacrylate inherently forms a gel upon exposure to water<sup>1</sup>.

### ***Claim Rejections - 35 USC § 103—new***

Claim 10, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizobuchi et al. (supra) as applied to claims 1, 2, 6, 7 and 13 above, and further in view of Dow et al., (US 5,061,700).

Mizobuchi et al. differs from the instant claim 10 insofar as it does not teach adding sugars in an amount of 5% to 70%.

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<sup>1</sup> See Horkay et al., "Osmotic and SANS Observations on Sodium Polyacrylate Hydrogels in Physiological Salt Solutions." *Macromolecules* 2000:33:8329-8333. The reference shows that sodium polyacrylate forms a gel after exposure to water and would be expected to do so (inherently) in a physiological salt solution.

Dow et al. teach the use of sucrose distearate as well as sorbitan sequioleate as surfactants for use in their topical ointment. (See col. 4, lines 6-12.) Dow also teaches the use of povidone iodine, as an antimicrobial drug at 10% wt, as per claims, 14 and 15. (See col. 6, lines 4-11, and lines 29-30.) Dow et al. does not teach a composition of claim 1.

Generally, it is obvious to replace one component for another equivalent component if it is recognized in the art that two components are equivalent and is not based on the Applicant's disclosure. See MPEP 2144.06. It is also *prima facie* obvious to select a known material based on its suitability for its intended use. See *Ibid*.

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to use the sucrose distearate of Dow in the composition of Mizobuchi since sucrose distearate is recognized as equivalent to sorbitan sequioleate, a surfactant taught in Mizobuchi. (See col. 4, lines 1-11.)

Mizobuchi teaches adding surfactants at 7%, as per claim 10. (See *id.*)

In regard to claims 14 and 15, it would have also been obvious to incorporate an antibacterial agent such as povidone iodine into the composition of Mizobuchi, since the artisan would have been motivated to prevent the growth of bacteria in the ointment to ensure that the ointment does not cause infection if applied to an open wound.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612